

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Denny, et al.  
Serial No. : 10/551,612  
Filed : September 30, 2005  
Title : CARIES RISK TEST FOR PREDICTING AND ASSESSING THE RISK OF DISEASE

Art Unit : 1641  
Examiner : Unknown

**Mail Stop Amendment**

Commissioner for Patents  
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Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. publications and issued patents below are not enclosed since it is no longer required to submit copies of these documents under 37 C.F.R. § 1.98(a)(2).

***U.S. Patents and U.S. Patent Publication***

1. U.S. Patent No. 4,692,407
2. U.S. Patent No. 4,725,576
3. U.S. Patent No. 4,768,238
4. U.S. Patent No. 5,013,542
5. U.S. Patent No. 5,103,836
6. U.S. Patent No. 5,112,758
7. U.S. Patent No. 5,268,148
8. U.S. Patent No. 5,335,673

**CERTIFICATE OF MAILING BY EXPRESS MAIL**

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Applicant : Denny, et al.  
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Page : 2 of 10

Attorney's Docket No.: 19644-005US1

9. U.S. Patent No. 5,374,538
10. U.S. Patent No. 5,376,532
11. U.S. Patent No. 5,585,241
12. U.S. Patent No. 5,631,228
13. U.S. Patent No. 5,646,119
14. U.S. Patent No. 5,486,503
15. U.S. Patent No. 5,695,929
16. U.S. Patent No. 5,714,341
17. U.S. Patent No. 5,736,322
18. U.S. Patent No. 5,736,341
19. U.S. Patent No. 5,756,361
20. U.S. Patent No. 5,801,226
21. U.S. Patent No. 5,807,541
22. U.S. Patent No. 5,830,489
23. U.S. Patent No. 5,866,432
24. U.S. Patent No. 5,885,965
25. U.S. Patent No. 5,886,054
26. U.S. Patent No. 5,910,122
27. U.S. Patent No. 5,912,230

- 28. U.S. Patent No. 5,968,746
- 29. U.S. Patent No. 6,063,588
- 30. U.S. Patent No. 6,130,042
- 31. U.S. Patent No. 6,136,298
- 32. U.S. Patent No. 6,230,052
- 33. U.S. Patent No. 6,231,857
- 34. U.S. Patent No. 6,436,721
- 35. U.S. Patent Publication No. 2003/0040009

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- 39. Ayad, M., et al. (2000). The association of basic proline-rich peptides from human parotid gland secretions with caries experience. *J. Dent. Res.* 79(4):976-982.
- 40. Bagán, J.V., et al. (1991). Recurrent aphthous stomatitis. A study of the clinical characteristics of lesions in 93 cases. *J. Oral Pathol. Med.* 20(8):395-397.
- 41. Beck, J.D. (1996). Periodontal implications: older adults. *Ann. Periodontol* 1(1):322-357.
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This Information Disclosure Statement is being submitted within three (3) months of the filing date or before any office action is issued. Consequently, no fee is required pursuant to 37 C.F.R. §1.97(b).

By citing the above references, Applicants do not acquiesce or admit that any of these documents is "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

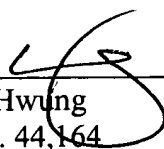
Applicant : Denny, et al.  
Serial No. : 10/551,612  
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Page : 10 of 10

Attorney's Docket No.: 19644-005US1

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Respectfully submitted,

Date: July 14, 2006

  
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Attorney's Docket No.

19644-005US1

Application No.

10/551,612

**Information Disclosure Statement  
by Applicant**

(Use several sheets if necessary)

Applicant

Denny, et al.

Filing Date

September 30, 2005

Group Art Unit

1641

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,692,407	09/08/1987	Jordan, et al.			
	AB	4,725,576	02/16/1988	Pollock, et al.			
	AC	4,768,238	09/06/1988	Kleinberg, et al.			
	AD	5,013,542	05/07/1991	Hay, et al.			
	AE	5,103,836	04/14/1992	Goldstein, et al.			
	AF	5,112,758	05/12/1992	Fellman, et al.			
	AG	5,268,148	12/07/1993	Seymour			
	AH	5,335,673	08/09/1994	Goldstein, et al.			
	AI	5,374,538	12/20/1994	Bratthall			
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	AK	5,585,241	12/17/1996	Lindmo			
	AL	5,631,228	05/20/1997	Oppenheim, et al.			
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	AR	5,736,341	04/07/1998	Sorsa, et al.			
	AS	5,756,361	05/26/1998	Winterbottom, et al.			
	AT	5,801,226	09/01/1998	Cummins, et al.			
	AU	5,807,541	09/15/1998	Aberg, et al.			
	AV	5,830,489	11/03/1998	Valenti, et al.			
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	AAA	5,912,230	06/15/1999	Oppenheim, et al.			

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 19644-005US1	Application No. 10/551,612
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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	ABB	5,968,746	10/19/1999	Schneider			
	ACC	6,063,588	05/16/2000	Lamster			
	ADD	6,130,042	10/10/2000	Diehl, et al.			
	AEE	6,136,298	10/24/2000	Gaffar, et al.			
	AFF	6,230,052	05/08/2001	Wolff, et al.			
	AGG	6,231,857	05/15/2001	Shi, et al.			
	AHH	6,436,721	08/20/2002	Kuo, et al.			
	AII	2003/0040009	02/27/2003	Denny, et al.			

Other Documents (include Author, Title, Date, and Place of Publication)		
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	AJJ	Akinyinka, O.O., et al. (2000). The effects of acute falciparum malaria on the disposition of caffeine and the comparison of saliva and plasma-derived pharmacokinetic parameters in adult Nigerians. <i>Eru. J. Clin. Pharmacol.</i> 56(2):159-165.
	AKK	Astor, F.C., et al. (1999). Xerostomia: a prevalent condition in the elderly. <i>Ear Nose Throat J.</i> 78(7):476-479.
	ALL	Atkinson, J.C., et al. (1993). "Guidelines for saliva nomenclature and collection," in <i>Saliva as a Diagnostic Fluid</i> , Ann. NY Acad. Sciences 694:xi-xii.
	AMM	Ayad, M., et al. (2000). The association of basic proline-rich peptides from human parotid gland secretions with caries experience. <i>J. Dent. Res.</i> 79(4):976-982.
	ANN	Bagán, J.V., et al. (1991). Recurrent aphthous stomatitis. A study of the clinical characteristics of lesions in 93 cases. <i>J. Oral Pathol. Med.</i> 20(8):395-397.
	AOO	Beck, J.D. (1996). Periodontal implications: older adults. <i>Ann. Periodontol</i> 1(1):322-357.
	APP	Beck, J., et al. (1996). Periodontal disease and cardiovascular disease. <i>J. Periodontol</i> 67(10 Suppl):1123-1137.
	AQQ	Belce, A., et al. (2000). Evaluation of salivary sialic acid level and Cu-Zn superoxide dismutase activity in type 1 diabetes mellitus. <i>Tohoku J. Exp. Med.</i> 192(3):219-225.
	ARR	Bobek, L.A., et al. (1996). Structure and chromosomal localization of the human salivary mucin gene, MUC7. <i>Genomics</i> 31(3):277-282.
	ASS	Bolscher, J.G., et al. (1999). Detection and quantification of MUC7 in submandibular, sublingual, palatine, and labial saliva by anti-peptide antiserum. <i>J. Dent. Res.</i> 78(7):1362-1369.

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<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Denny, et al.	
		Filing Date September 30, 2005	Group Art Unit 1641

Other Documents (include Author, Title, Date, and Place of Publication)		
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	ATT	Caton, J. (1989). Periodontal diagnosis and diagnostic aids. In Proceedings of the World Workshop in Clinical Periodontics. Princeton, NJ: American Academy of Periodontology; I:1-22.
	AUU	Chang, F., et al. (1990). Detection of human papillomavirus (HPV) DNA in oral squamous cell carcinomas by in situ hybridization and polymerase chain reaction. Arch. Dermatol. Res. 282(8):493-497.
	AVV	Daniels, T.E., and Fox, P.C. (1992). Salivary and oral components of Sjögren's syndrome. Rheum Dis Clin North Am. 18(3):571-589.
	AWW	de Villiers, E.M. (1989). Papilloma viruses in cancers and papillomas of the aerodigestive tract. Biomed Pharmacother. 43(1):31-36.
	AXX	Denny, P.C., et al. (2006). A novel saliva test for caries risk assessment. CDA Journal 34(4):287-294.
	AYY	Dusek, M., et al. (1996). Masticatory function in patients with xerostomia. Gerodontology 13(1):3-7.
	AZZ	Ellen, R.P. (1976). Microbiological assays for dental caries and periodontal disease susceptibility. Oral Sci Rev. 8:3-23.
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	ADDD	Ferguson, M.M., et al. (1984). An epidemiological study of factors associated with recurrent aphthae in women. J. Oral Med. 39(4):212-217.
	AEEE	Fox, P.C., et al. (1985). Xerostomia: evaluation of a symptom with increasing significance. J Am Dent Assoc. 110(4):519-525.
	AFFF	Franceschi, S., et al. (1996). Human papillomavirus and cancers of the upper aerodigestive tract: a review of epidemiological and experimental evidence. Cancer Epidemiol Biomarkers Prev. 5(7):567-575.
	AGGG	Genco, R.J. (1990). Classification of clinical and radiographic features of periodontal diseases. In Genco, R., Goldman, H., Cohen, W., eds. Contemporary Periodontics. St. Louis: pp. 63-81.
	AHHH	Genco, R.J. (1996). Current view of risk factors for periodontal diseases. J Periodontol. 67(10 Suppl):1041-1049.
	AIII	Gendler, S.J., and Spicer, A.P. (1995). Epithelial mucin genes. Annu Rev Physiol. 57:607-634.
	AJJJ	Gibbs, R.S., et al. (1992). A review of premature birth and subclinical infection. Am J Obstet Gynecol. 166(5):1515-1528.
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<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Denny, et al.	
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Other Documents (include Author, Title, Date, and Place of Publication)		
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	AKKK	Hayes, C., et al. (1998). The association between alveolar bone loss and pulmonary function: the VA dental longitudinal study. <i>Ann Periodontol.</i> 3(1):257-261.
	ALLL	Hillier, S.L., et al. (1988). A case-control study of chorioamnionic infection and histologic chorioamnionitis in prematurity. <i>N Engl J Med.</i> 319(15):972-978.
	AMMM	Hillier, S.L., et al. (1995). Association between bacterial vaginosis and preterm delivery of a low-birth-weight infant. <i>N Engl J Med.</i> 333(26):1737-1742.
	ANNN	Hume, W.R. (1993). Need for change in standards of caries diagnosis—perspective based on the structure and behavior of the caries lesion. <i>J Dent Educ.</i> 57(6):439-443.
	AOOO	Igarashi, T., et al. (1996). Direct detection of <i>Streptococcus mutans</i> in human dental plaque by polymerase chain reaction. <i>Oral Microbiol Immunol.</i> 11(5):294-298.
	APPP	Institute of Medicine, Committee to Study the Prevention of Low Birth Weight, Division of Health. Promotion and Disease Progression. Preventing low birth weight. Washington: National Academy Press (1985)
	AQQQ	Klein, A., et al. (1992). Progress of HIV infection and changes in the lipid membrane structure of CD4+ cells. <i>AIDS</i> 6(3):332-333.
	ARRR	Kline, M.W. (1996). Oral manifestations of pediatric human immunodeficiency virus infection: a review of the literature. <i>Pediatrics.</i> 97(3):380-388.
	ASSS	Lenander-Lumikari, M., and Loimaranta, V. (2000). Saliva and dental caries. <i>Adv Dent Res.</i> 14:40-47.
	ATTT	Lehner, T. (1968). Autoimmunity in oral diseases, with special reference to recurrent oral ulceration. <i>Proc R Soc Med.</i> 61(5):515-524.
	AUUU	Löe, H. (1993). Periodontal disease. The sixth complication of diabetes mellitus. <i>Diabetes Care.</i> 16(1):329-334.
	AVVV	Mandel, I.D., and Gaffar, A. (1986). Calculus revisited. A review. <i>J Clin Periodontol.</i> 13(4):249-257.
	AWWW	Mandel, I.D. (1993). Salivary diagnosis: promises, promises. <i>Ann N Y Acad Sci.</i> 694:1-10.
	AXXX	Mandel, I.D. (1995). Calculus update: prevalence, pathogenicity and prevention. <i>J Am Dent Assoc.</i> 126(5):573-580.
	AYYY	Mealey, B.L. (1996). Periodontal implications: medically compromised patients. <i>Ann Periodontol.</i> 1(1):256-321.
	AZZZ	McCullough, M.J., et al. (1996). <i>Candida albicans</i> : a review of its history, taxonomy, epidemiology, virulence attributes, and methods of strain differentiation. <i>Int J Oral Maxillofac Surg.</i> 25(2):136-144.
	AAAAA	Miller, A.J., et al. (1987). Oral health of United States adults: national findings. National Institute of Dental Research, U.S. Department of Health and Human Services. NIH Publication No. 87:2868.

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	ABBBB	Najera, M.P., et al. (1997). Prevalence of periodontal disease in patients with Sjögren's syndrome. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 83(4):453-457.
	ACCCC	Diabetes statistics. NIH Publication No. 99-3892. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases, March 1999.
	ADDDD	Navazesh, M. (1993). Methods for collecting saliva. Ann N Y Acad Sci. 694:72-77.
	AEEEE	Newbrun, E., and Leverett, D. (1990). Risk assessment dental caries working group summary statement. In Risk Assessment in Dentistry. J.D. Bader, ed., Chapel Hill, N.C.: University of North Carolina, pp. 304-305.
	AFFFF	Nielsen, P.A., et al. (1996). Differential expression of human high-molecular-weight salivary mucin (MG1) and low-molecular-weight salivary mucin (MG2). J Dent Res. 75(11):1820-1826.
	AGGGG	Nolan, A., et al. (1991). Recurrent aphthous ulceration: vitamin B1, B2 and B6 status and response to replacement therapy. J Oral Pathol Med. 20(8):389-391.
	AHHHH	Offenbacher, S., et al. (1996). Periodontal infection as a possible risk factor for preterm low birth weight. J Periodontol. 67(10 Suppl):1103-1113.
	AIIII	Offner, G.D., and Troxler, R.F. (2000). Heterogeneity of high-molecular-weight human salivary mucins. Adv Dent Res. 14:69-75.
	AJJJJ	Oxholm, P., and Asmussen, K. (1996). Primary Sjögren's syndrome: the challenge for classification of disease manifestations. J Intern Med. 239(6):467-474.
	AKKKK	Park, N.H., et al. (1995). Combined oral carcinogenicity of HPV-16 and benzo(α)pyrene: an <i>in vitro</i> multistep carcinogenesis model. Oncogene. 10(11):2145-2153.
	ALLLL	Payne, J.B., et al. (1997). The association between estrogen status and alveolar bone density changes in postmenopausal women with a history of periodontitis. J Periodontol. 68(1):24-31.
	AMMMM	Powell, L.V. (1998). Caries prediction: a review of the literature. Community Dent Oral Epidemiol. 26(6):361-371.
	ANNNN	Prakobphol, A., et al. (1999). Separate oligosaccharide determinants mediate interactions of the low-molecular-weight salivary mucin with neutrophils and bacteria. Biochemistry. 38(21):6817-6825.
	AOOOO	Rayment, S.A., et al. (2000). Immunoquantification of human salivary mucins MG1 and MG2 in stimulated whole saliva: factors influencing mucin levels. J Dent Res. 79(10):1765-1772.
	APPPP	Romero, R., et al. (1993). The relationship between spontaneous rupture of membranes, labor, and microbial invasion of the amniotic cavity and amniotic fluid concentrations of prostaglandins and thromboxane B <sub>2</sub> in term pregnancy. Am J Obstet Gynecol. 168(6 Pt 1):1654-1668.

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	AQQQQ	Saah, A.J., et al. (1992). Predictors of the risk of development of acquired immunodeficiency syndrome within 24 months among gay men seropositive for human immunodeficiency virus type 1: a report from the Multicenter AIDS Cohort Study. <i>Am J Epidemiol.</i> 135(10):1147-1155.
	ARRRR	Samaranayake, L.P., and Holmstrup, P. (1989). Oral candidiasis and human immunodeficiency virus infection. <i>J Oral Pathol Med.</i> 18(10):554-564.
	ASSSS	Scannapieco, F.A., et al. (1998). Associations between oral conditions and respiratory disease in a national sample survey population. <i>Ann Periodontol.</i> 3(1):251-256.
	ATTTT	Scannapieco, F.A., and Mylotte, J.M. (1996). Relationships between periodontal disease and bacterial pneumonia. <i>J Periodontol.</i> 67(10 Suppl):1114-1122.
	AUUUU	Schenkein, H.A., and Van Dyke, T.E. (1994). Early-onset periodontitis: systemic aspects of etiology and pathogenesis. <i>Periodontol</i> 2000. 6:7-25.
	AVVVV	Scully, C., and Porter, S.R. (1989). Recurrent aphthous stomatitis: current concepts of etiology, pathogenesis and management. <i>J Oral Pathol Med.</i> 18(1):21-27.
	AWWWW	Seemann, R., et al. (2001). Differences in the salivary glycan pattern between children with high and low caries susceptibility. <i>Caries Res.</i> 35(2):156-161.
	AXXXX	Shapiro, S., et al. (1980). Relevance of correlates of infant deaths for significant morbidity at 1 year of age. <i>Am J Obstet Gynecol.</i> 136(3):363-373.
	AYYYY	Sharon, N. (1996). Carbohydrate-lectin interactions in infectious disease. <i>Adv Exp Med Biol.</i> 408:1-8.
	AZZZZ	Ship, I.I. (1965). Inheritance of aphthous ulcers of the mouth. <i>J Dent Res.</i> 44(5):837-844.
	AAAAAA	Socransky, S.S., and Haffajee, A.D. (1992). The bacterial etiology of destructive periodontal disease: current concepts. <i>J Periodontol.</i> 63(4 Suppl):322-331.
	ABBBBB	Steinfeld, S., et al. (2000). Labeled neoglycoproteins and human lectins as diagnostic and potential functional markers in salivary glands of patients with Sjögren's syndrome. <i>J Rheumatol.</i> 27(8):1910-1916.
	ACCCCC	Strous, G.J., and Dekker, J. (1992). Mucin-type glycoproteins. <i>Crit Rev Biochem Mol Biol.</i> 27(1-2):57-92.
	ADDDDD	Sugerman, P.B., and Shillitoe, E.J. (1997). The high risk human papillomaviruses and oral cancer: evidence for and against a causal relationship. <i>Oral Dis.</i> 3(3):130-147.
	AEEEEEE	Suzuki, J.B. (1988). Diagnosis and classification of the periodontal diseases. <i>Dent Clin North Am.</i> 32(2):195-216.
	AFFFFFF	Svojanovsky, S.R., et al. (1999). High sensitivity ELISA determination of taxol in various human biological fluids. <i>J Pharm Biomed Anal.</i> 20(3):549-555.
	AGGGGG	Syrjänen, S.M., et al. (1988). Human papillomavirus (HPV) DNA sequences in oral precancerous lesions and squamous cell carcinoma demonstrated by <i>in situ</i> hybridization. <i>J Oral Pathol.</i> 17(6):273-278.

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	AHHHHH	Tanzer, J.M. (1997). Understanding dental caries: an infectious disease, not a lesion. Internat. J. Oral Biol. 22(4):205-214.
	AIIII	Talal, N. (1992). Sjögren's syndrome: historical overview and clinical spectrum of disease. Rheum Dis Clin North Am. 18(3):507-515.
	AJJJJ	Tindall, et al. (1995). Primary HIV infection: clinical, immunologic, and serologic aspects. Medical Management of AIDS, Sande, et al., eds., pp. 105-129; W.B. Saunders, 1995.
	AKKKKK	National Institute of Health Consensus Development Panel. National Institutes of Health Consensus Development Conference statement. Diagnosis and management of dental caries throughout life, March 26-28, 2001. J Am Dent Assoc. (2001) 132(8):1153-1161.
	ALLLLL	Van Dyke, T.E., et al. (1980). Neutrophil chemotaxis dysfunction in human periodontitis. Infect Immun. 27(1):124-132.
	MMMMM	Wheeler, Jr., C.E. (1988). The herpes simplex problem. J Am Acad Dermatol. 18(1 Pt 2):163-168.
	ANNNNN	Whitley, R.J. (1992). Neonatal herpes simplex virus infections: pathogenesis and therapy. Pathol Biol (Paris). 40(7):729-734.
	AOOOOO	Wintergerst, U., et al. (2000). Use of saliva specimens for monitoring indinavir therapy in human immunodeficiency virus-infected patients. Antimicrob Agents Chemother. 44(9):2572-2574.
	APPPPP	Woo, S.B., and Sonis, S.T. (1996). Recurrent aphthous ulcers: a review of diagnosis and treatment. J Am Dent Assoc. 127(8):1202-1213.

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